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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,202	04/13/2006	Osamu Honmou	033873-0108	4131

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,202	HONMOU ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/05; 4/06; 7/06; 6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-13 are pending. Claims 1-13 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all the inventors, received on 13 April 2006 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 23 December 2005, 13 April 2006, 14 July 2006, and 6 June 2007 consisting of 3 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a 371 of PCT/JP04/09386 (filed 06/25/2004). The application also claims benefit from foreign application JAPAN 2003-185260 (filed 06/27/2003) and JAPAN 2003-432329 (filed 12/26/2003). The instant application has been granted the benefit date, 25 June 2004, from the application PCT/JP04/09386.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected because "a mesenchymal cell introduced with a BDNF gene" is unclear. The metes and bounds of the claims are unclear. Is the mesenchymal cell co-administered with a gene therapy vector comprising BDNF? Or has the mesenchymal cell been treated ex-vivo with a gene therapy vector comprising BDNF prior to delivery to the subject? Or, perhaps, the mesenchymal cell which was introduced into a subject naturally expresses the BDNF gene product? Clarification of this phrase is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahmood et al (Neurosurgery, Vol.49, No.5, November 2001: 1196-1204).

Claim 1 is directed to a cranial nerve disease therapeutic agent for in vivo administration, comprising a mesenchymal cell as an active ingredient.

Claim 2 is directed to the agent of claim 1, wherein the cranial nerve disease is cerebral infarction.

Claim 3 is directed to an agent for in vivo administration, exhibiting neuroprotection and comprising a mesenchymal cell as an active ingredient.

Claim 4 is directed to an agent for in vivo administration, exhibiting cranial nerve regeneration and comprising a mesenchymal cell as an active ingredient.

Claim 5 is directed to the agent of claim 1, wherein the in vivo administration is intravenous.

Claim 7 is directed to the agent of claim 1, wherein the mesenchymal cell is a mesenchymal stem cell.

Claim 8 is directed to the agent of claim 1, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell.

Claim 9 is directed to a method for treating a cranial nerve disease comprising the in vivo administration to a patient of a therapeutically effective amount of the agent of claim 1.

Claim 10 is directed to the method of claim 9, wherein the bone marrow cell is an autologous cell of the patient.

Claim 11 is directed to the method of claim 9 , wherein the cranial nerve disease is cerebral infarction.

Claim 12 is directed to the method of claim 9, wherein the in vivo administration is intravenous administration.

Claim 13 is directed to the method of claim 9, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell.

Mahmood et al. teach, "transplantation studies in cerebral ischemia, functional outcome was significantly improved in MSC-transplanted rats compared with bone marrow-transplanted animals....Bone marrow or MSCs transplanted directly into the striatum and cortex of rat brain subjected to TBI or middle cerebral artery occlusion migrate...induce neurological and functional improvement...Intravenous transplantation has the advantage of carrying the cells over a much wider area." (page 1196, col.2). MSC is an acronym for marrow stromal cells. Mesenchymal progenitor cells are components of bone marrow stroma. Mahmood et al. specifically describe mesenchymal cells administered by IV methods (page 1200, col.2). The limitations of claims 1-5 and 7-13 are met by Mahmood et al.

Accordingly, Mahmood et al. anticipated the instant claims.

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Twardzik et al (US2002/0123465, published 5 September 2002).

Claim 1 is directed to a cranial nerve disease therapeutic agent for in vivo administration, comprising a mesenchymal cell as an active ingredient.

Claim 2 is directed to the agent of claim 1, wherein the cranial nerve disease is cerebral infarction.

Claim 3 is directed to an agent for in vivo administration, exhibiting neuroprotection and comprising a mesenchymal cell as an active ingredient.

Claim 4 is directed to an agent for in vivo administration, exhibiting cranial nerve regeneration and comprising a mesenchymal cell as an active ingredient.

Claim 5 is directed to the agent of claim 1, wherein the in vivo administration is intravenous.

Claim 7 is directed to the agent of claim 1, wherein the mesenchymal cell is a mesenchymal stem cell.

Claim 8 is directed to the agent of claim 1, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell.

Claim 9 is directed to a method for treating a cranial nerve disease comprising the in vivo administration to a patient of a therapeutically effective amount of the agent of claim 1.

Claim 10 is directed to the method of claim 9, wherein the bone marrow cell is an autologous cell of the patient.

Claim 11 is directed to the method of claim 9 , wherein the cranial nerve disease is cerebral infarction.

Claim 12 is directed to the method of claim 9, wherein the in vivo administration is intravenous administration.

Claim 13 is directed to the method of claim 9, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell.

Twardzik et al. teach, "one type of progenitor cells used for therapeutic applications are those derived from the mesenchyme. Mesenchymal progenitors give rise to a very large number of distinct tissues." (parag. 0102). Twardzik et al. further teach "mesenchymal stem cells from bone marrow" (parag.0103). Twardzik et al. teach, "in another embodiment of the invention mesenchymal progenitor cells are used in cell replacement therapy" (parag.0136). Twardzik et al. further teach the cells are autologous. Twardzik et al. also teach the intravenous administration of stem cells (parag.0138). Twardsik et al. teach, "the vectors may be used to deliver polynucleotides to cells ex vivo such as cells explanted form an individual patient...bone marrow aspirates...or universal donor hematopoietic stem cells, followed by reimplantation of the cells into a patient, usually after selection for the cells which have incorporated the polynucleotide" (parag.0147). Twardzik et al. also teach that neural stem cells are useful for treating CNS ischemic disease (e.g., stroke or brain attack). (parag.0108)

Accordingly, Twardzik et al. anticipated the instant claims.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gold et al (US2002/0168766, published 14 November 2002).

The agent of claims 1-5 and 7-8 directed to mesenchymal cells is taught by Gold et al., "mesenchymal cells differentiated from hES cells" (parag.0100).

Claim 6 is directed to the agent of claim 1, wherein the mesenchymal cell is: (a) a mesenchymal cell introduced with a BDNF gene, PLGF gene, GDNF gene, or IL-2 gene; or (b) an immortalized mesenchymal cell introduced with an hTERT gene. Gold et al. disclose, "mesenchymal cells differentiated from hES cells" (parag.0100). Gold et al. also teach methods of creating stable genetic alterations of cells (parag.0051). Gold et al. teach, "optionally, differentiated human PS cells suitable for conditioning medium can be further adapted—for example by genetically altering the cells to express a growth factor like bFGF, or to express TERT, or to immortalize the cells" (parag.0102). Gold et al. also teach, "Other reasons to genetically alter stem cells is to immortalize them by providing an expression system for the catalytic component of telomerase (TERT), or otherwise genetically adapt them for an in vitro use such as drug screening. For therapeutic applications, it may be beneficial to modify cells with therapeutic genes," (parag. 0146). Gold et al. further teach the BDNF.

Accordingly, Gold et al. anticipated the instant claims.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JLE